



UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 16 2006

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

SYNNESTVEDT & LECHNER LLP
2600 ARAMARK TOWER
1101 MARKET STREET
PHILADELPHIA PA 19107-2950

In re Application of :
Young Mi Choi-ledeski et al :
Serial No.: 09/918,039 : PETITION DECISION
Filed: July 30, 2001 :
Attorney Docket No.: P24,450-E :

This is in response to the petition under 37 CFR 1.144, filed July 5, 2006, requesting withdrawal of an improper restriction requirement. The delay in acting on this petition is regretted, but it was only recently forwarded for decision.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 and contained 42 claims, as filed. Claims 3-5, 7, 13, 15-21 and 42 were canceled and most other claims amended prior to action by the examiner. The examiner mailed a restriction requirement to applicants on September 24, 2002, requiring only an election of species. Applicants replied on November 13, 2002, identifying a species for examination purposes.

The examiner mailed an Office action to applicants on January 24, 2003, acknowledging the elected species, and rejecting claims 1-2, 6, 8-12, 21-25 and 28-41 under 35 U.S.C. 112, second paragraph, as indefinite. Applicants replied on May 23, 2003, amending claims 1, 22, 24-25 and 29 and canceling claim 23, and responding to the examiner's rejection.

The examiner then suspended prosecution on the application for a period of six months on August 11, 2003.

The examiner resumed prosecution on May 18, 2004, by mailing a new Office action rejecting the same claims under 35 U.S.C. 112, second paragraph, and rejecting claims 1, 6, 8-12, 14, 25 and 28-30 under 35 U.S.C. 102(e) as anticipated by Salvino et al. Applicants replied on August 20, 2004, by amending claims 1-2, 8, 11, 25 and 29. Applicants also replied to each of the rejections of record.

On December 2, 2004, the examiner mailed a restriction requirement to applicants setting forth a 17 way restriction, as follows:

Groups I-V – claims 1-2, 6, 8-12, 14, 22 and 24-34, drawn to compounds where Ar¹ is pyrrolo[2,3-c]pyridine and where R² is: (I) SO₂-phenyl or -naphthyl; (II) SO₂-(5-member heteroaryl or heterocycle); (III) SO₂-(6-member heteroaryl); (IV) SO₂-quinolyl; or (V) SO₂-benzopyranyl;

Groups VI-X – claims 1-2, 6, 8-12, 14, 22 and 24-34, drawn to compounds where Ar¹ is pyrrolo[2,3-b]pyridine and where R² is: (VI) SO₂-phenyl or -naphthyl; (VII) SO₂-(5-member heteroaryl or heterocycle); (VIII) SO₂-(6-member heteroaryl); (IX) SO₂-quinolyl; or (X) SO₂-benzopyranyl;

Groups XI-XV – claims 1-2, 6, 8-12, 14, 22 and 24-34, drawn to compounds where Ar¹ is pyrrolo[3,2-c]pyridine and where R² is: (XI) SO₂-phenyl or -naphthyl; (XII) SO₂-(5-member heteroaryl or heterocycle); (XIII) SO₂-(6-member heteroaryl); (XIV) SO₂-quinolyl; or (XV) SO₂-benzopyranyl;

Group XVI – claims 1-2, 6, 8-12, 14, 22 and 24-34, drawn to compounds where Ar¹ and R² are not as defined above.

Group XVII – claims 35-41, drawn to the combination therapy and/or composition comprising additional agents.

The examiner set forth reasons for restriction and held specifically that Groups I-XVI were unrelated because they do not have the same core or R². Possible further restriction was indicated for the last two groups, if elected.

Applicants replied on April 7, 2005, canceling claims 1-34 and 42 and amending claims 35-41, and traversing the restriction requirement as improper as all compounds have a common core and have a common property or activity. By cancellation of all other claims, Group XVII was elected.

The examiner mailed a non-Final Office action to applicants on June 27, 2005, acknowledging applicants' election and making a further 16 way restriction requirement of claims 35-41 based on the R² group and the orientation of the pyrrolopyridine fused ring structure similar to that set forth above for Groups I-XV and identifying Group XVI as directed to any other compounds not encompassed by Groups I-XV and subject to further restriction. The examiner used the same reasoning as before for justifying the restriction requirement.

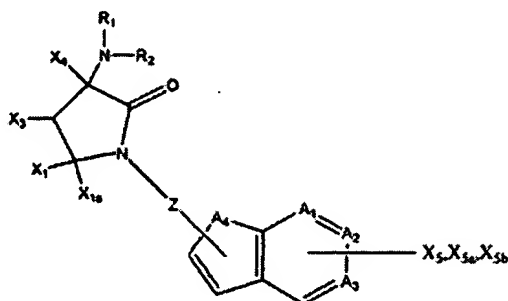
Applicants replied on September 22, 2005, arguing that the restriction requirement is improper for the same reasons as before and electing Group XVI and a specific compound as before.

The examiner mailed a non-Final Office action to applicants on December 30, 2005, responding to applicants' traversal and maintaining the requirement. The examiner then further restricted the elected Group into two additional groups based on the specific pyrrolopyridine system and the value of R³ in the R² variable and held the former constructively elected. Claims 35-41 were then rejected under 35 U.S.C. 112, second paragraph, as indefinite and under first paragraph, as lacking enablement.

Applicants replied on June 30, 2006, amending claims 35, 37-39 and 41 and responding to the rejections and filing this petition.

DISCUSSION

Applicants' claims are directed to compounds having the following structure:



The compounds are identified as aminopyrrolidinone-pyrrolopyridine compounds. As defined in the claims, the fused pyrrolopyridine structure contains four variables, A₁-A₄ with A₄ always being a nitrogen (i.e. an N-R) group and only one of A₁-A₃ being a nitrogen. The Z-aminopyrrolidinone structure may be attached to the fused ring at any available carbon and X₅, X_{5a} and X_{5b} are defined as one being proximal (i.e. – adjacent) to and one being distal (remote) from the ring the Z moiety is attached to and alpha to the nitrogen of that ring with the last occupying any other position available. Each represents a different set of values with some overlap. Z is an alkenyl group, C_r-C(O)-N(R)-C_s, C_r-N(R)-C(O)-C_s, or C_r-N(R)-C_s where r is 1 or 2 and s is 0, 1 or 2. X₁, X_{1a}, X₃ and X₄ are generally defined as alkyls, aryls, heteroaryl or combinations thereof with additional substitution or as combining to form an additional ring. R₁ and R₂ are similarly defined and may contain further variables R₃-R₇ and may combine to form a ring also.

It is noted that the title of the application does not appear to reflect the compounds currently being claimed as sulfur appears only in a few radicals and is not required to be present in any radical. Correction should be made.

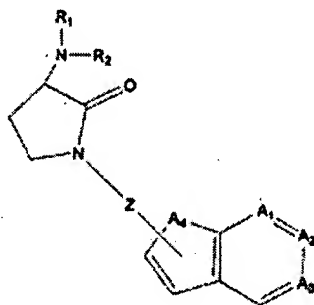
Claims 35-38 are directed to a method of treatment using the pharmaceutical compounds based on the above structure in combination with another specific type of drug and claims 39-42 are directed to the pharmaceutical compounds, *per se*, in combination with another specific drug. As can be seen there are three distinct pyrrolo-pyridine structures depending on the location of the nitrogen in the pyridine ring (as defined by the examiner). There are also six possible points of attachment of the Z structure and this dictates the location of two other radicals.

The prosecution history shows that at least three formal restriction requirements have been made during the prosecution of this application (September 24, 2002 – election of species only; December 2, 2004 – 17-way restriction; June 27, 2005 – 16-way restriction; December 30, 2005 – 2-way restriction). Except for the first election of species requirement each restriction requirement has further narrowed the examined subject matter. It is not the general policy of the Office to make multiple restriction requirements. Here for purposes of restriction the examiner has focused on the fused pyrrolo-pyridine ring and the R² moiety which is as remote from the pyrrolo-pyridine ring as possible as providing the basis for restriction.

Applicants' petition only addresses the most recent restriction requirements holding that they are improper and referring to M.P.E.P. 803.02. Applicants argue that the restriction requirements between Groups I-V, VI-X and XI-XV should be withdrawn. Each of these groups is directed to a specific pyrrolo-pyridine structure and further restriction is based on the value of R^2 .

Applicants point to the fact that the examiner has indicated that classification of all of the groups of compounds falls in Classes 514 and 546, thus indicating no burden is presented in searching all of the compounds. Further, the examiner has not pointed to any difference in activity of the compounds pertaining to the different values of R^2 . However, the examiner has limited the value of R^2 to an $S(O)_1$ or $_2R^3$ moiety in the restriction requirement whereas R^2 can have many other different values not involving $S(O)_x$ substituents. Thus the restriction requirement is flawed on its face by not including all possible compounds within the Groups set forth.

Applicants suggest that the following should be considered the substantial structural feature which provides unity of invention within the claims:



Applicants' suggestion is appropriate except that R_1 and R_2 should not have been included. What then is considered the core structure has only variables A_1 - A_3 , only one of which can be nitrogen and the exact point of attachment of the Z moiety. This then provides three different pyrrolo-pyridine structures between which restriction may be required as has essentially been done by the examiner. While classification of the three structures may be similar or the same search of each of the structures would be different, especially when searching various data bases. (It may not, however, be unexpected to find all three pyrrolo-pyridine structures in a single reference.)

Based on the above, the restriction requirement is restructured as three groups, Group I, where A_1 is N; Group II, where A_2 is N; and Group III, where A_3 is N. Applicants' election of a single disclosed species is also confirmed and examination will continue based on that election. No further restriction can or will be made based on the election of species made. Examination will proceed on the elected species to determine its patentability, and if patentable the examination will be expanded to consider other related species in order to determine the patentability of the particular pyrrolo-pyridine compounds encompassed by the election of species.

Although applicants argue that all three pyrrolo-pyridine ring structures should be examined together, as explained above the differences between the different structures is sufficient to establish a search burden on the Office based on the need to search commercial databases and other sources to determine patentability.

DECISION

The petition is **GRANTED-IN-PART**. The restriction requirement is redrafted as above with three groups based on the different pyrrolo-pyridine ring structures. No other variables are considered in making this requirement.

The application will be forwarded to the examiner for consideration of applicants' reply filed June 30, 2006, and further action not inconsistent with this decision.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 703-308-3824 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott
Director, Technology Center 1600